

## From the INTERNATIONAL SEARCHING AUTHORITY

# PCT

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To: KILBURN & STRODE , Attn. Bassil, Nichol 20 Red Lion Street	as C.		NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION
London WC1R 4PJ UNITED KINGDOM			(PCT Rule 44.1)
-	•	= 1 KAT	2004 2 6 JAN 2005
		6,	Date of mailing (day/month/year) 01/03/2004
Applicant's or agent's file reference P32590WO/NCB		5/3	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No.	1		International filing date
PCT/GB 03/03192			(day/month/year) 25/07/2003
Applicant			
ROSLIN INSTITUTE (ED	INBURGH)		

1.	$\mathbf{x}$	The appl	icant is hereby n	notified that the International Search Report has been established and is transmitted herewith.
				and statement under Article 19: if he so wishes, to amend the claims of the International Application (see Rule 46):
		When?		or filing such amendments is normally 2 months from the date of transmittal of the earch Report; however, for more details, see the notes on the accompanying sheet.
		Where?	Directly to the	International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Fascimile No.: (41-22) 740.14.35
		For mor	e detailed instru	uctions, see the notes on the accompanying sheet.
2.				notified that no International Search Report will be established and that the declaration under ect is transmitted herewith.
3.		With reg	ard to the prote	est against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
				with the decision thereon has been transmitted to the International Bureau together with the to forward the texts of both the protest and the decision thereon to the designated Offices.
		no no	decision has bee	en made yet on the protest; the applicant will be notified as soon as a decision is made.
4.	Furt	ner action	n(s): The appl	icant is reminded of the following:
	If the	né applica prity claim	nt wishes to avo , must reach the	he priority date, the international application will be published by the International Bureau. oid or postpone publication, a notice of withdrawal of the international application, or of the International Bureau as provided in Rules 90 <i>bis</i> .1 and 90 <i>bis</i> .3, respectively, before the reparations for international publication.
	Withi wis	n 19 mor hes to po	ths from the price stpone the entry	ority date, a demand for international preliminary examination must be filed if the applicant into the national phase until 30 months from the priority date (in some Offices even later).
•	bef	ore all de	signated Offices	ority date, the applicant must perform the prescribed acts for entry into the national phase which have not been elected in the demand or in a later election within 19 months from the elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Barbara Klaver

Authorized officer



These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

#### **INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19**

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new:
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

# The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
   "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
  - "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

#### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

## It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

## Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

#### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.





(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	1 (Form PCT/ISA/2	of Transmittal of International Search Report (220) as well as, where applicable, item 5 below.
P32590WO/NCB	ACTION (1.011117.01719.22	
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/GB 03/03192	25/07/2003	26/07/2002
Applicant		-
ROSLIN INSTITUTE (EDINBURG	SH)	
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this International Searching Autl Insmitted to the International Bureau.	hority and is transmitted to the applicant
This International Search Report consists	of a total of 10 sheets.	
	a copy of each prior art document cited in this	report.
Basis of the report      With regard to the language, the i	international search was carried out on the ba	sis of the international application in the
language in which it was filed, unli	ess otherwise indicated under this item.	sis of the international application in the
the international search w Authority (Rule 23.1(b)).	as carried out on the basis of a translation of t	he international application furnished to this
		nternational application, the international search
was carried out on the basis of the contained in the internation	e sequence listing : anal application in written form.	
filed together with the inte	rnational application in computer readable for	m.
X furnished subsequently to	this Authority in written form.	
X furnished subsequently to	this Authority in computer readble form.	
	osequently furnished written sequence listing one is the sequence listing of t	does not go beyond the disclosure in the
X the statement that the info furnished	ormation recorded in computer readable form i	is identical to the written sequence listing has been
2. X Certain claims were fou	nd unsearchable (See Box I).	
3. X Unity of invention is lac	king (see Box II).	
4. With regard to the title,		
X the text is approved as su	bmitted by the applicant.	
the text has been establis	hed by this Authority to read as follows:	
		•
5. With regard to the abstract,		
X the text is approved as su	bmitted by the applicant.	
	hed, according to Rule 38:2(b), by this Author e date of mailing of this international search re	ity as it appears in Box III. The applicant may, port, submit comments to this Authority.
6. The figure of the drawings to be publ	ished with the abstract is Figure No.	1
as suggested by the appli	icant.	None of the figures.
X because the applicant fail	ed to suggest a figure.	
because this figure better	characterizes the invention.	





Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	ernational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. χ	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
	As far as claims 13 to 21 are directed to a diagnostic method practised on the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Inte	rnational Searching Authority found multiple inventions in this international application, as follows:
	see additional sheet
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. X	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
	1-6 9-21
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark o	on Protest The additional search fees were accompanied by the applicant's protest.
	No protest accompanied the payment of additional search fees.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6, 9-21 (all partially)

A nucleic acid construct comprising (i) a nucleic acid sequence encoding a member of the lipocalin protein family, and (ii) a nucleic acid sequence encoding a peptide sequence of from 5 to 250 amino acid residues; said nucleic acid construct when the lipocalin is ovine betalactoglobulin (BLG) (accession No X12817); a host cell with said nucleic acid construct; a transgenic non-human animal in which the cells of the non human animal express the protein encoded by said nucleic acid construct; the use of said nucleic acid construct for detection of a gene activation event resulting from a change in an altered metabolic status in a cell in vitro or in vivo; a method for the detection of a gene activation event in a cell in vitro or in vivo, comprising assaying a host cell stably transfected with said nucleic acid construct, wherein said ovine betalactoglobulin is heterologous to the cell in which it is expressed, or a transgenic non-human animal, whose cells expressed such a construct, in which the cell or animal is subjected to a gene activation event that is signalled by expression of a peptide tagged ovine BLG reporter gene;

2. claims: 1-6, 9-21 (all partially)

A nucleic acid construct comprising (i) a nucleic acid sequence encoding murine major urine protein (MUP) (accession No NM 031188) and (ii) a nucleic acid sequence encoding a peptide sequence of from 5 to 250 amino acid residues; a host cell with said nucleic acid construct; a transgenic non-human animal in which the cells of the non human animal express the protein encoded by said nucleic acid construct; the use of said nucleic acid construct for detection of a gene activation event resulting from a change in an altered metabolic status in a cell in vitro or in a method for the detection of a gene activation event in a cell in vitro or in vivo, comprising assaying a host cell stably transfected with said nucleic acid construct, wherein said murine MUP is heterologous to the cell in which it is expressed, or a transgenic non-human animal, whose cells expressed such a construct, in which the cell or animal is subjected to a gene activation event that is\_signalled\_by\_expression\_of\_a\_peptide\_tagged\_murine\_MUP\_ reporter gene;

3. claims: 1-6, 9-21 (all partially)

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A nucleic acid construct comprising (i) a nucleic acid sequence encoding rat alpha-2-urinary globulin (alpha -2u) (accession number M27434) and (ii) a nucleic acid sequence encoding a peptide sequence of from 5 to 250 amino acid residues; a host cell with said nucleic acid construct; a transgenic non-human animal in which the cells of the non human animal express the protein encoded by said nuclaic acid construct; the use of said nucleic acid construct for detection of a gene activation event resulting fromm a change in an altered metabolic status in a cell in vitro or in vivo; a method for the detection of a gene activation event in a cell in vitro or in vivo, comprising assaying a host cell stably transfected with said nucleic acid construct, wherein said rat alpha-2-urinary globulin (alpha -2u) is heterologous to the cell in which it is expressed, or a transgenic non-human animal, whose cells expressed such a construct, in which the cell or animal is subjected to a gene activation event that is signalled by expression of a peptide tagged rat alpha-2-urinary globulin (alpha -2u) reporter gene;

## 4. claims: 7-8 and partially 9-21

A nucleic acid construct comprising a stress inducible promoter operatively isolated from a nucleic acid sequence encoding a member of the lipocalin protein family by a nucleic acid sequence flanked by nucleic acid sequence s recognised by a sire specific recombinase, or by insertion such that it is inverted with respect to the transcription unit encoding a member of the lipocalin ptotein family, in which the construct additionnally comprises a nucleic acid sequence comprising a tissue specific promoter operatively linked to a gene encoding the coding sequence for the site specific recombinase; a host cell with said nucleic acid construct; a transgenic non-human animal in which the cells of the non human animal express the protein encoded by said nucleic acid construct; the use of said nucleic acid construct for detection of a gene activation event resulting from a change in an altered metabolic status in a cell in vitro or in vivo; a method for the detection of a gene activation event in a cell in vitro or in vivo, comprising assaying a host cell stably transfected with said nucleic acid construct, wherein said lipocalin is heterologous to the cell in which it is expressed, or a transgenic non-human animal, whose cells expressed such a construct, in which the cell or animal is subjected to a gene activation event that is\_signalled\_by\_expression\_of\_a\_peptide\_tagged\_lipocalin. reporter gene

5. claims: 15-16, 18 (all partially)



The use of a nucleic acid construct comprising a nucleic acid sequence encoding a member of the lipocalin protein family, wherein said lipocalin protein is heterologous to the cell in which it is expressed, for the detection of a gene activation event resulting from a change in altered metabolic status in a cell in vitro or in vivo; a method for the detection of a gene activation event in a cell in vitro or in vivo, comprising essaying a host cell stably transfected with a nucleic acid construct comprising a nucleic acid sequence encoding a member of the lipocalin protein family, wherein said lipocalin protein is heterologous to the cell in which it is expressed, or a transgenic non-human animal, whose cells expressed such a construct, in which the cell or animal is subjected to a gene activation event that is signalled by expression of a peptide tagged lipocalin reporter gene, as far as not covered by a previous subject;

## 6. claim: 18 (partially)

A method for the detection of a gene activation event in a cell in vitro or in vivo, comprising essaying a host cell stably transfected with a nucleic acid construct comprising a nucleic acid sequence encoding a member of the lipocalin protein family, wherein said lipocalin protein is heterologous to the cell in which it is expressed, or a transgenic non-human animal, whose cells expressed such a construct, in which the cell or animal is subjected to a gene activation event that is signalled by expression of a peptide tagged lipocalin reporter gene, as far as not covered by a previous subject;

Internional Application No PC v 03/03192

A. CLASSIFICATION OF SUBJECT MA

BJECT MA 52 Co-K14/47

C12Q1/68

G01N33/68

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 C12N C07K G01N C12Q A01K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Refevant to claim No.
Х	MCCLENAGHAN M ET AL: "Insertion of a casein kinase recognition sequence induces phosphorylation of ovine beta-lactoglobulin in transgenic mice" PROTEIN ENGINEERING, vol. 12, no. 3, March 1999 (1999-03), pages 259-264, XP002259482 ISSN: 0269-2139	1,2,9-12
v	cited in the application the whole document	3,4
'	the whole document	, ,,,
X	WO 02/053701 A (LAREYRE JEAN-JACQUES; UNIV VANDERBILT (US); MATUSIK ROBERT J (US); OR) 11 July 2002 (2002-07-11)	1
Υ	figure 7; example 12	3,4
	-/	

A Public documents are listed at the Continuation of box C.	A Palent family members are usted in annex.				
Special categories of cited documents:      A* document defining the general state of the art which is not considered to be of particular relevance.	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention				
"E" earlier document but published on or after the international filing date  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled				
citation or other special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other means					
"P" document published prior to the international filling date but later than the priority date claimed	in the art. "%" document member of the same patent family				
Date of the actual completion of the international search	. Date of mailing of the international search report				
16 February 2004	0 1 03 2004				
Name and mailing address of the ISA	Authorized officer				
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Chambonnet, F				

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PC 1 03/03192

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x	SCHLEHUBER STEFFEN ET AL: "A novel type of receptor protein, based on the lipocalin scaffold, with specificity for digoxigenin" JOURNAL OF MOLECULAR BIOLOGY, LONDON, GB, vol. 297, no. 5, 14 April 2000 (2000-04-14), pages 1105-1120, XP002150338 ISSN: 0022-2836	1,3,5,9
Υ	page 1112, column 1, paragraph 2 - page 1115, column 2, paragraph 4; figures 2,10,11	3,4
X	WO 00/75308 A (SKERRA ARNE ; SCHLEHUBER STEFFEN (DE)) 14 December 2000 (2000-12-14)	1,2,5
Y	the whole document	3,4
x	SUI DEXIN; WILSON JOHN E: "Interaction of insulin-like growth factor binding protein-4, Miz-1, leptin, lipocalin-typprostaglandin D synthase, and granulin precursor with the N-terminal half of Type III -hexokinase"  ARCHIVES OF BIOCHEMISTRY AND BIOPHYSICS, vol. 382, no. 2, 15 October 2000 (2000-10-15), pages 262-274, XP0001172430 the whole document	
x	SUNDARAM M ET AL: "Expression, characterization and engineered specificity of rat epididymal retinoic-acid binding protein" BIOCHEMICAL JOURNAL, PORTLAND PRESS, LONDON, GB, vol. 334, no. 1, 15 August 1998 (1998-08-15), pages 155-160, XP002095127 ISSN: 0264-6021 page 156, column 1, paragraph 2 - column 2, paragraph 2; figure 1	1
	-/	
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Intermional Application No

		PC 03/03192
C.(Continu	ation) DOCUMENTS CONS	37,0132
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
х	SCHMIDT A M ET AL: "A ZN(II)-BINDING SITE ENGINEERED INTO RETINOL-BINDING PROTEIN EXHIBITS METAL-ION SPECIFICITY AND ALLOWS HIGHLY EFFICIENT AFFINITY PURIFICATION WITH A NEWLY DESIGNED METAL LIGAND" CHEMISTRY AND BIOLOGY, CURRENT BIOLOGY, LONDON, GB, vol. 3, no. 8, August 1996 (1996-08), pages 645-653, XP001117565 ISSN: 1074-5521 page 647, column 2, paragraph 3 - page 648, column 1, paragraph 3	1
X	US 6 114 123 A (BAUGHN MARIAH R ET AL) 5 September 2000 (2000-09-05) the whole document	1,9-12
x	CROSSETT, B. ET AL.: "Transfer of a uterine lipocalin from the endometrium of the mare to the developing equine conceptus" BIOLOGY OF REPRODUCTION, vol. 59, 1998, pages 483-490, XPO02259483 the whole document	
A	WO 97/07132 A (COMMW SCIENT IND RES ORG; WANG LINFA (AU)) 27 February 1997 (1997-02-27)	1,3,4,9
Y	the whole document	3,4
Υ	US 5 948 677 A (JARVIK JONATHAN W) 7 September 1999 (1999-09-07) the whole document	3,4
A	WO 98/30715 A (ISACOFF EHUD Y ; SIEGAL MICAH S (US); UNIV CALIFORNIA (US); CALIFORNIA) 16 July 1998 (1998-07-16)	1,9-21
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Interional Application No
PC 03/03192

C (Continue	ation) DOCUMENTS CONS	03/03192
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Α	EP 1 111 387 A (JAPAN SCIENCE & TECH CORP ; OSAKA BIOSCIENCE INST (JP); MARUHA CORP (J) 27 June 2001 (2001-06-27)	21
x	the whole document WO 02/31151 A (BRUNS CHRISTOPHER M; HAFALIA APRIL J A (US); INCYTE GENOMICS	1,3, 15-18
Y	INC (US)) 18 April 2002 (2002-04-18) page 1, line 27 - page 2, line 27 page 33, line 35 - page 34, line 12 page 41, line 12 - line 24 page 44, line 33 - page 45, line 30 page 51, line 29 - page 52, line 34 page 68, line 35 - page 69, line 11; claims 7,8,20,23,27-29	15-18

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nformation on patent family members

internional Application No
PC 03/03192
amily Publication

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			MO	0201949		10-01-200
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WO 0231151	Α	18-04-2002	AII			
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